

RESPONSE

Serial No. 09/954,586  
Atty. Docket No. GP116-03.UT

**Marked-Up Version of Amendments**

**IN THE CLAIMS:**

The claims have been amended as follows:

1. (Amended) A hybridization assay probe comprising an oligonucleotide which hybridizes to a target sequence present in nucleic acid derived from a *Cryptosporidium parvum* organism in a test sample under stringent conditions to form a probe:target hybrid stable for detection, said oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in the target sequence, wherein the target sequence is selected from the group consisting of [SEQ ID NO:5,] SEQ ID NO:6, [SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9,] SEQ ID NO:10, [SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13,] SEQ ID NO:14[, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17,] and SEQ ID NO:18, [SEQ ID NO:19 and SEQ ID NO:20,] and wherein said probe does not hybridize to nucleic acid derived from a *Cryptosporidium muris*, *Cryptosporidium baileyi* or *Crptosporidium wrairi* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

20. (Amended) A hybridization assay probe comprising an oligonucleotide which hybridizes to a target sequence present in nucleic acid derived from a *Cryptosporidium parvum* organism in a test sample under stringent conditions to form a probe:target hybrid stable for detection, [wherein the base sequence of] said oligonucleotide having a base sequence which is at least 80% complementary to the base sequence of the target sequence, wherein the target sequence has a base sequence selected from the group consisting of [SEQ ID NO:5,] SEQ ID NO:6, [SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9,] SEQ ID NO:10, [SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13,] SEQ ID NO:14[, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17,] and SEQ ID NO:18, [SEQ ID NO:19 and SEQ ID NO:20,] and wherein said probe does not hybridize to nucleic acid

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derived from a *Cryptosporidium muris*, *Cryptosporidium baileyi* or *Crptosporidium wrairi* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

21. (Amended) An oligonucleotide probe which hybridizes to a target sequence present in nucleic acid derived from a *Cryptosporidium parvum* organism in a test sample under stringent conditions to form a probe:target hybrid stable for detection, wherein the base sequence of said probe is at least 80% complementary to the base sequence of the target sequence, wherein the target sequence is selected from the group consisting of [SEQ ID NO:5,] SEQ ID NO:6, [SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9,] SEQ ID NO:10, [SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13,] SEQ ID NO:14[, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17,] and SEQ ID NO:18, [SEQ ID NO:19 and SEQ ID NO:20,] and wherein said probe does not hybridize to nucleic acid derived from a *Cryptosporidium muris*, *Cryptosporidium baileyi* or *Crptosporidium wrairi* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

22. (Amended) An oligonucleotide probe which hybridizes to a target sequence present in nucleic acid derived from a *Cryptosporidium parvum* organism in a test sample under stringent conditions to form a probe:target hybrid stable for detection, wherein the base sequence of said probe is fully complementary to the base sequence of the target sequence, wherein the target sequence is selected from the group consisting of [SEQ ID NO:5,] SEQ ID NO:6, [SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9,] SEQ ID NO:10, [SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13,] SEQ ID NO:14[, SEQ ID NO:15, SEQ ID NO:16, SEQ ID NO:17,] and SEQ ID NO:18, [SEQ ID NO:19 and SEQ ID NO:20,] and wherein said probe does not hybridize to nucleic acid derived from a *Cryptosporidium muris*, *Cryptosporidium baileyi* or *Crptosporidium wrairi* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

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23. (Amended) A probe mix comprising the probe of claim 1 and [one or more] a first helper oligonucleotide [oligonucleotides, each said helper oligonucleotide] having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence selected from the group consisting of SEQ ID NO:29, [SEQ ID NO:30, SEQ ID NO:31, SEQ ID NO:32,] SEQ ID NO:33, [SEQ ID NO:34, SEQ ID NO:35, SEQ ID NO:36,] SEQ ID NO:37[, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40,] and SEQ ID NO:41[, SEQ ID NO:42, SEQ ID NO:43 and SEQ ID NO:44].

29. (Amended) The probe mix of claim 23[, wherein:  
the target sequence of said probe is selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:17 and SEQ ID NO:18; and

said one or more helper oligonucleotides include first and] further comprising a second helper [oligonucleotides] oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence[, wherein the target sequence of said first helper oligonucleotide is selected from the group consisting of SEQ ID NO:29, SEQ ID NO:33, SEQ ID NO:37 and SEQ ID NO:41, and wherein the target sequence of said second helper oligonucleotide is] selected from the group consisting of SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:40 and SEQ ID NO:44.

38. (Amended) The method of claim 37 further comprising providing to the test sample [one or more] a first amplification [primers] primer under amplification conditions, [each] said first primer comprising an oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence[, wherein the target sequence is] selected from the group consisting of [SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:47,] SEQ ID NO:48, [SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ

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ID NO:52, SEQ ID NO:53,] SEQ ID NO:54, [SEQ ID NO:55, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:59,] SEQ ID NO:60[, SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65,] and SEQ ID NO:66, [SEQ ID NO:67 and SEQ ID NO:68,] and wherein said primer optionally includes a 5' sequence which is recognized by an RNA polymerase or which enhances initiation or elongation by an RNA polymerase.

39. (Amended) The method of claim 38[,] further comprising providing to the test sample a second amplification primer comprising an oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence [wherein the target sequence of one of said primers is] selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

40. (Amended) The method of claim 38[,] further comprising providing to the test sample a second amplification primer comprising an oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence [wherein the target sequence of one of said primers is] selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

53. (Amended) A kit comprising, in packaged combination, [said oligonucleotide of claim 34 and one or more] first and second oligonucleotides for use in determining the presence of a *Cryptosporidium parvum* organism in a test sample, each of said oligonucleotides having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence contained in nucleic acid derived from a *Cryptosporidium parvum* organism. wherein:

the target sequence of said first oligonucleotide is selected from the group consisting of SEQ ID NO:6, SEQ ID NO:10, SEQ ID NO:14 and SEQ ID NO:18;

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the target sequence of said second oligonucleotide is selected from the group consisting of [SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:47,] SEQ ID NO:48, [SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53,] SEQ ID NO:54, [SEQ ID NO:55, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:59,] SEQ ID NO:60[, SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65,] and SEQ ID NO:66[, SEQ ID NO:67 and SEQ ID NO:68, wherein said primer] and

said second oligonucleotide optionally includes a 5' sequence which is recognized by an RNA polymerase or which enhances initiation or elongation by an RNA polymerase.

59. (Amended) The kit of claim 53 [54, wherein:] further comprising a third oligonucleotide, wherein said third oligonucleotide has an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence contained in nucleic acid derived from a *Cryptosporidium* organism, and wherein

[the target sequence of said first third oligonucleotide is selected from the group consisting of SEQ ID NO:6, SEQ ID NO:10, SEQ ID NO:14 and SEQ ID NO:18; and]

the target sequence of said [second] third oligonucleotide is selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

60. (Amended) The kit of claim 53 [54, wherein:] further comprising a third oligonucleotide, wherein said third oligonucleotide has an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence contained in nucleic acid derived from a *Cryptosporidium* organism, and wherein

[the target sequence of said first oligonucleotide is selected from the group consisting of SEQ ID NO:6, SEQ ID NO:10, SEQ ID NO:14 and SEQ ID NO:18; and]

the target sequence of said [second] third oligonucleotide is selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

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84. (Amended) A kit comprising, in packaged combination, [said probe of claim 1 and at least one helper oligonucleotide] first and second oligonucleotides for use in determining the presence of a *Cryptosporidium parvum* organism in a test sample, each of said oligonucleotides having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence contained in nucleic acid derived from a *Cryptosporidium parvum* organism, wherein:

the target sequence of said first oligonucleotide is selected from the group consisting of SEQ ID NO:6, SEQ ID NO:10, SEQ ID NO:14 and SEQ ID NO:18; and

the target sequence of said second oligonucleotide is selected from the group consisting of SEQ ID NO:29, [SEQ ID NO:30, SEQ ID NO:31, SEQ ID NO:32,] SEQ ID NO:33, [SEQ ID NO:34, SEQ ID NO:35, SEQ ID NO:36,] SEQ ID NO:37[, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40,] and SEQ ID NO:41[, SEQ ID NO:42, SEQ ID NO:43 and SEQ ID NO:44].